WhaleTeq

Single Channel ECG Test System (SECG 4.0)

User Manual

For Software Revision 1.0.0.x

(Revision 2014-03-10)

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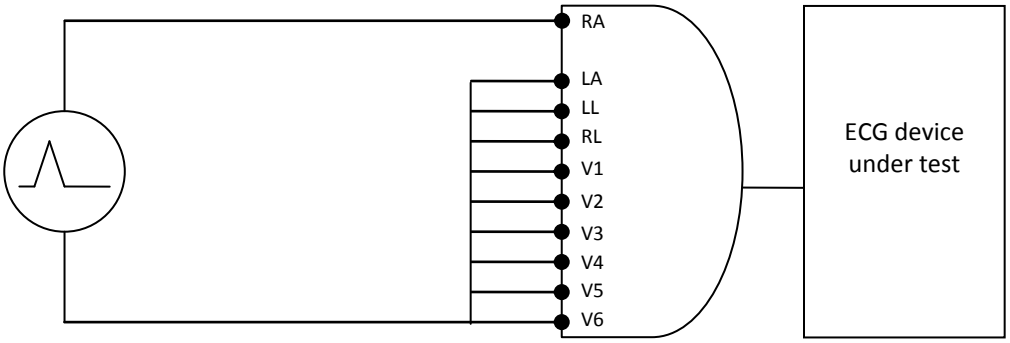
1 Introduction

1.1 Basic concept

The WhaleTeq Single Channel ECG Test System 4.0 provides a single waveform to one or more lead electrodes of diagnostic, ambulatory or monitoring ECGs, for testing to IEC particular standards. The following diagram shows the single channel concept:



(Figure 1) Single channel concept

Via a USB module, the system produces arbitrary waveforms (streamed from the PC with digital to analogue conversion) at up to ±5V, which is then applied to a precision 1000:1 divider to produce the voltages at up to ±5mV level (10mVpp). The USB module contains resistor/capacitor networks, dc offset, pacing circuit and relay switching to provide the full range of single channel performance tests in IEC standards as described in Section1.2.

The basic range of tests in the standards include, for example:

- Sensitivity (accuracy of the mV/mm indication)
- Frequency response (sine wave, and impulse tests)
- Input impedance
- Noise
- Multichannel cross talk
- Accuracy of heart rate indication
- Pacemaker rejection
- Tall T-wave rejection

For a full list of tests, refer to the standard together with Section 1.2.

The system does not provide:

- CMRR tests (this requires a special noise free box, available from WhaleTeq)
- Multichannel waveforms, such as the CTS Atlas, CSE, AHA, MIT databases (this requires a multichannel system, available from WhaleTeq)

1.2 Standards/Application

The following table shows the standards for which this system has been designed for, and includes any limitations:

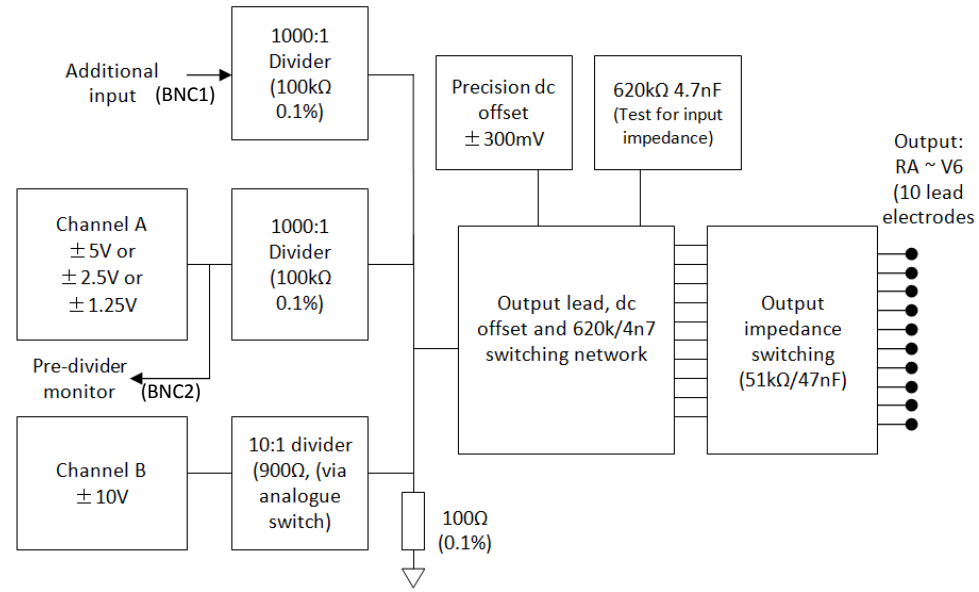
Standard	Clause(s)	Limitations / Notes
IEC 60601-2-25:2011 (diagnostic)	201.12.4: All performance tests except CMRR test and baseline noise (use WhaleTeq CMRR box for this), and any test referring to the CTS atlas (CAL/ANE waveforms, for this use WhaleTeq MECG) Note: for most tests CAL/ANE waveforms are alternates. For two tests may be required (201.12.4.102.3, test of lead networks; and 201.12.4.105.3 test of ringing from mains notch filter)	For 201.12.4.10 (large dc offset test), the SECG is limited to ±1Vdc. However, this is almost certainly enough to exceed the point of saturation. For the test circuit in figure 201.110, switch position A is not provided. This is considered an error in the standard due to the loading effect of R2. Instead the DC offset is provided in series with output as per Figure 201.106. (See section 3.2 for notes on switching between P1, P2 and P6.)
IEC 60601-2-27:2011 (patient monitoring)	201.7.9.2.9.101 b), 4) and 6) (special test waveforms for Figure 201.101) 201.12.1.101, all performance tests except baseline noise and CMRR (use WhaleTeq CMRR 2.0 box for these tests)	No known limitations
IEC 60601-2-47:2012 (ambulatory)	201.12.4, all tests except CMRR	No known limitations
ANSI/AAMI EC 13 2002/(R)2007/C2008	All performance tests except CMRR and as noted left.	See below for Clauses 5.1.4 n) and 5.2.9.1 f), g) [1]

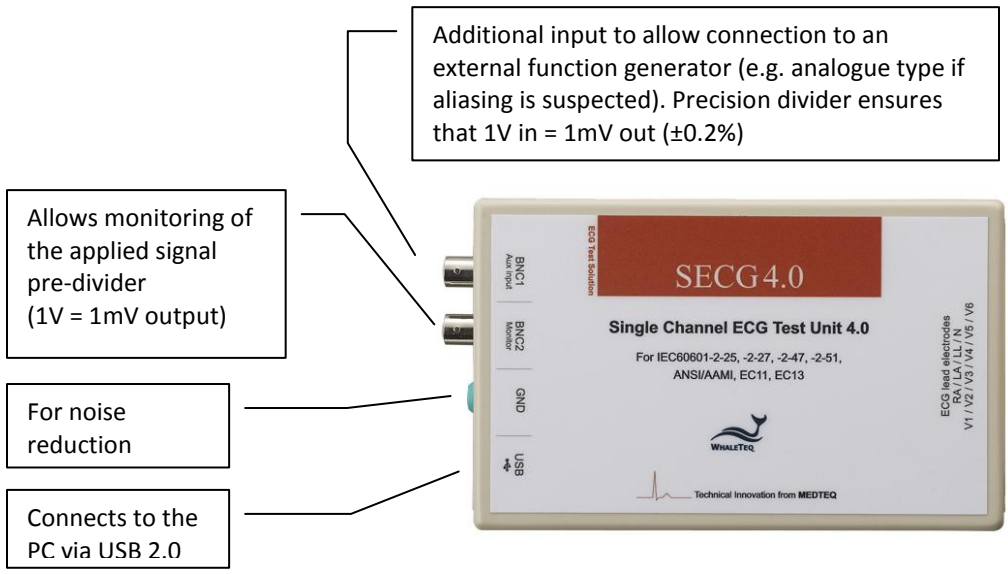
[1] 5.1.4 n) Fast QRS: The sampling rate is limited to 0.2ms, some distortion of the pulse is possible below 6ms.

General limitation: this equipment is designed for use with isolated ECG circuits, as are generally provided for medical ECG. If applied to a non-isolated circuit, the noise may be excessive.

1.3 Block diagram/USB Module overview

The following is a simplified block diagram of the system inside the USB module:


Additional input (BNC1)
1000:1 Divider (100kΩ 0.1%)
Precision dc offset ±300mV
620kΩ 4.7nF (Test for input impedance)
Output: RA ~ V6 (10 lead electrodes
Channel A ±5V or ±2.5V or ±1.25V
1000:1 Divider (100kΩ 0.1%)
Output lead, dc offset and 620k/4n7 switching network
Output impedance switching (51kΩ/47nF)
Pre-divider monitor (BNC2)
Channel B ±10V
10:1 divider (900Ω, (via analogue switch)
100Ω (0.1%)


Additional input to allow connection to an external function generator (e.g. analogue type if aliasing is suspected). Precision divider ensures that 1V in = 1mV out (±0.2%)
Allows monitoring of the applied signal pre-divider (1V = 1mV output)
For noise reduction
Connects to the PC via USB 2.0
BNC1 Aux Input
BNC2 Monitor
GND
USB
ECG Test Solution
SECG4.0
Single Channel ECG Test Unit 4.0
For IEC60601-2-25, -2-27, -2-47, -2-51, ANSI/AAMI, EC11, EC13
WHALETEQ
Technical Innovation from MEDTEQ
ECG lead electrodes
RA / LA / LL / N
V1 / V2 / V3 / V4 / V5 / V6

5. 2.9.1 f), g): Functionality is not included at this time; note the test is not applicable to most ECG systems

1.4 Main specifications

In general, the system has been designed to the standards above, taking into account Clause 4.6 in IEC 60601-2-27 and IEC 60601-2-47. Below includes these parameters and also other system parameters necessary for testing. For reference the system capability is provided.

Parameter	Specification	System capability / notes
Main output voltage accuracy	±1% for amplitudes of 0.5mVpp or higher	±0.3%
Main output voltage resolution (DAC resolution)	2.5µV	In version 4.0, a single output range is used
Frequency / pulse repetition rate accuracy	±1%	±0.1%
Pulse duration / timing accuracy (excluding pacing)	±1ms	±0.2ms
Pacing pulse width accuracy	±5µs	±1µs
Pacing pulse amplitude accuracy, range	±2mV pulse: ±1% >2mV pulse: ±10% Range: ±2mV to ±700mV	±2mV pulse: ±0.3% 100mV pulse: ±1% or ±5mV
Pacing pulse characteristics	Rise/fall time 5µs Overshoot <1% Settling time <1%	
Pacing pulse overshoot (intentional)	Method A according to IEC 60601-2-27	
Resistor tolerance	±2%	±0.5%
Capacitor tolerance	±10%	±5%
Precision 1000:1 divider	±0.3%	±0.1%
Sample rate	5kHz ± 0.1%	5kHz ± 0.05% (50ppm)
DC offset (fixed, noise free, sourced from internal super capacitor)	300mV ± 1%	300mV ±0.1%
DC offset (variable, may include up to 50µVpp noise)	Setting ±1% or ±3mV	Setting ±1% or ±3mV

Power supply	USB +5Vdc supply (no separate power supply required) 0.5A (high power mode)	Typical load<0.25A, up to 0.45A is possible if all relays are turned on
Environment	15 ~ 30°C (by design, not tested) 30 ~ 80% RH (design not tested)	Selection of components is such that no effect from the environment is expected.
Safety, EMC standards	No applicable safety standards (maximum internal voltages 12Vdc) For EMC no testing performed. CE marking based on careful selection of parts, including USB protection IC, as well as special filters to reduce noise from microprocessor (8MHz) and DC/DC converter (200kHz). Due to the low volume of production, testing is not warranted.	

Additional specifications may be provided on request.

1.5 Revision history

2011-11-23	Software upgrade for the following: • Correct setting of T-wave amplitude during Auto Pacing mode (previous software set this to 0.0mV, should be 0.2mV) • Correct mode selection (due to addition of ANSI/AAMI exponential waveform in the main function list, some automated features selected the incorrect mode).
2011-09-26	Software upgrade for the following: • Added functions for ANSI/AAMI EC 13
2011-08-11	Software upgrade for the following: • Reduction in streaming interruptions • Software controlled calibration procedure • Added new software functions for IEC 60601-2-27:2011 (heart rate testing) • Updated software functions to better suit IEC 60601-2-51
2012-09-07	Editorial corrections; add new section for options
2012-07-19	Updated for SECG 4.0
2012-08-29	Corrected editorial errors (change pictures, diagrams to SECG 4.0), and added section on terminals P1, P2 and P6

2 Set up

2.1 Software installation

2.1.1 System requirements

The Single Channel ECG system uses a normal PC to interface and control the USB module. The PC should meet the following requirements:

- Windows PC (XP or later)
- Microsoft .NET 2.0 or higher
- Administrator access (if necessary for installation of software/driver)
- 512MB RAM or higher[2]
- Free USB port

2.1.2 PC Software installation

Software can be installed directly from the WhaleTeq website

There are three options provided:

- Direct installation from the internet (if compatible with network/system)
- Copy zip file to PC and run “setup.exe” file
- Copy zip file to PC, change “setup.abc” file to “setup.exe” and run (this option is provided for systems that may block “.exe” extensions)

The current software is based on .NET 2.0 which is intended for broad compatibility.

2.1.3 USB driver installation

The system uses a USB mode called “CDC” which emulates a serial COM port for which Microsoft Windows® already has the driver for this installed. However, it is necessary to link the test unit to this driver, which follows a process similar to installing a driver.

A copy of the linking file “mchpcdc.inf” can be downloaded from WhaleTeq website. When the USB module is first connected, select manual installation, and point to folder containing the above linking file. Continue to follow instruction. There may be a warning that the driver is not recognized by Windows® which can be ignored. This linking file is provided by Microchip® for use with PIC microprocessors having in built USB function.

[2] Relative to normal PC processing, there is no special use of PC speed. However, there has been noted a slow increase in system RAM usage over long periods of time up to 30-40MB (related to MS Windows “garbage collection”). PCs with only 512MB or less installed and are running several other programs (in particular, Internet Explorer), may exceed the available RAM, requiring access to the hard drive and dramatically impacting speed. In this case, streaming interruptions and other problems may occur.

2.2 Set up

Connect the USB module (test unit) to any USB socket of the PC. Note: if the socket is changed, it may take the PC a short amount of time to recognize and connect to the system.

Run the WhaleTeq Single Channel ECG software. If the USB module is not recognized, a message will be displayed. In this case, repeat the process, ensuring sufficient time for the PC to recognize the USB module prior to starting the WhaleTeq software.

2.3 Connecting to the ECG

For connecting the ECG device under to the USB module, use the “ECG breakout box” provided. If purchase includes only the SECG, then the breakout box for 12 leads will have 10 terminals corresponding to RA, LA up to V6.

If the purchased set includes the WhaleTeq CMRR 2.0, then there may be additional terminals for CMRR use only, and also an additional breakout box only for CMRR purpose. This will depend on the set and standards selected. For SECG, use only the box marked for “General purpose”, and use only the terminals marked for RA ~ V6.

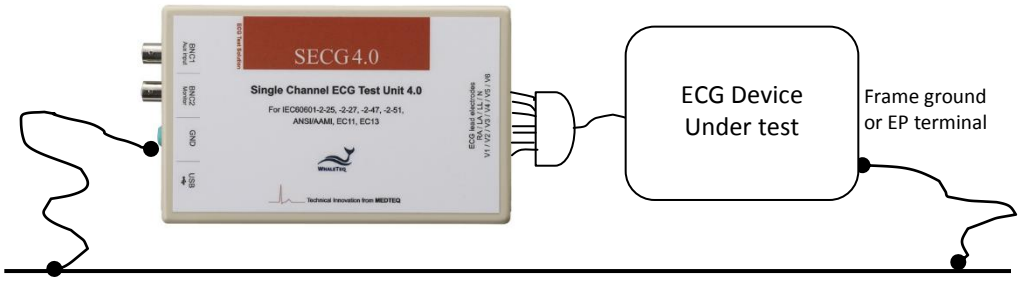
Alternately the ECG device under test can be directly connected to the USB module using a male D15 connector. The pin outs are:

1-RA	4 – RL	7 – V4	10 - V1
2-LA	5 –V6	8 – V3	11- NC
3-LL	6 – V5	9 – V2	12- GND

Note: for systems after 2011-09-10, V1 ~ V6 are reversed as shown above. Also pin 12 is the system ground.

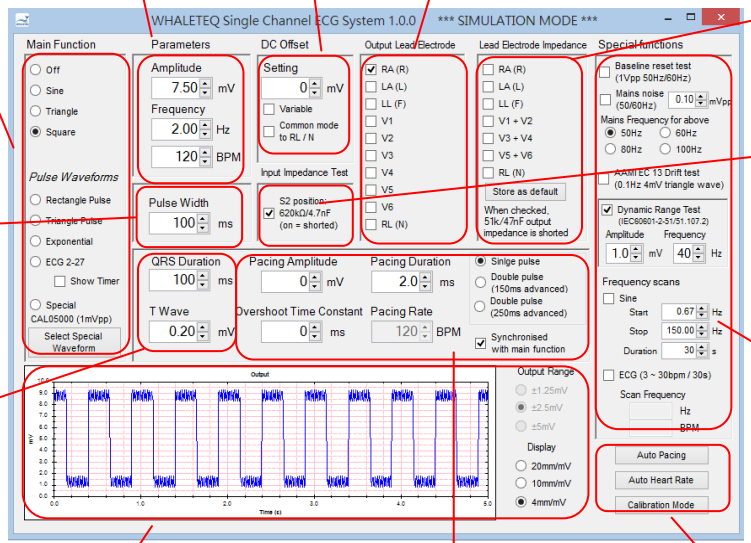
2.4 Environment, noise reduction

A noise free environment is necessary for testing ECG equipment. This can be achieved relatively easily by (a) using a metal bench or metal sheet underneath the ECG device under test and the WhaleTeq SECG test unit, and (b) connecting SECG GND terminal to the sheet and also the frame ground (or EP terminal) of the ECG device under test:



With this set up, turn the ECG device under test to maximum sensitivity, turn off the ac filters (if possible) and confirm that the level of noise is acceptable for tests. For most tests, this set up is satisfactory without any special efforts. However for the input impedance test with the 620kΩ is in series the imbalance in impedance can cause high noise. For this test, the ac filter may be turned on. If the noise is still excessive, move to an electrically quiet environment or increase the size of the metal sheet underneath and around the set up.

2.5 Main screen



Parameter settings

DC offset settings

Selects the lead electrode which the output is switched to

Selects the main function (waveform) type, such as sine, triangle, ECG etc

No longer used for Version 4.0

Selects if 620kΩ/4.7nF is in circuit (for input impedance test)

Selects the pulse width for rectangle and triangle pulse only

Special functions

Selects the parameters related to the ECG waveform (IEC 60601-2-27)

Provides a semi-real time graphical display of the current signal

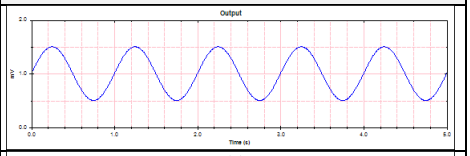
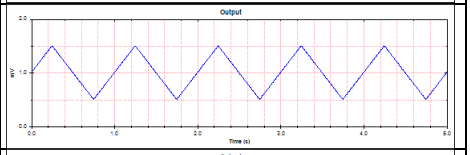
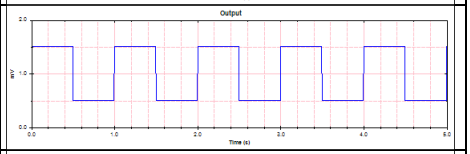
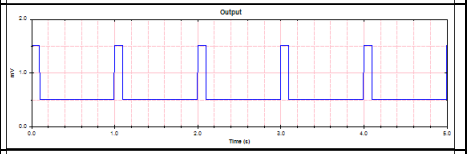
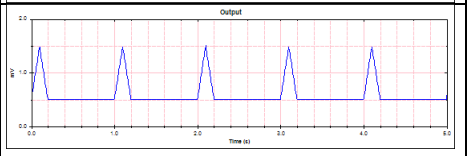
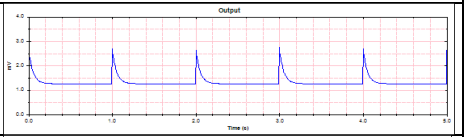
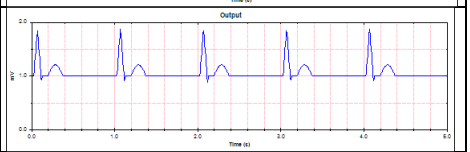
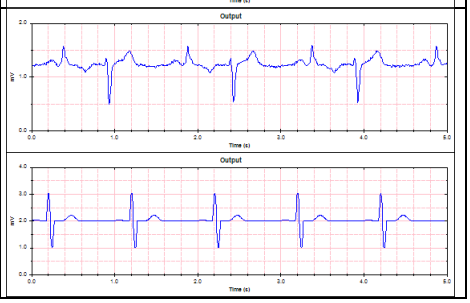
Parameters related to pacemaker pulses

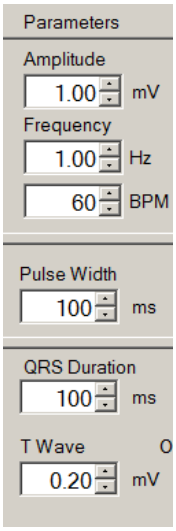
Automated functions

2.6 Description of Functional groups

2.6.1 Main function (main waveform)

This group allows the operator to select the main waveform to be used in the test, from the following:

Waveform type	Description	Sample waveform
Sine	Basic sine wave, according to the amplitude (mVpp) and frequency (Hz or bpm)	
Triangle	Basic triangle wave, according to the amplitude (in mVpp) and frequency (Hz or bpm)	
Square	Basic square wave, according to the amplitude (in mVpp) and frequency (Hz or bpm)	
Rectangle pulse	A rectangular pulse, according to the amplitude setting, pulse width and pulse repetition rate (frequency, Hz or bpm)	
Triangle pulse	A triangle pulse, according to the amplitude setting, base (pulse) width and pulse repetition rate (frequency, Hz or bpm)	
Exponential	Exponential waveform, used to test AAMI EC13 Clause 5.9.2.8 e), Hysteresis test (set amplitude to ±1.5mV, pulse width 50ms)	
ECG	Waveform according to IEC 60601-2-27, Figure 113 and 119, with adjustable parameters for amplitude (mVpp)	
Special	A range of stored waveforms including ANSI/AAMI waveforms for testing Clause 6.8 of IEC 60601-2-27, and some selected CAL waveforms from IEC 60601-2-51. For these waveforms, the amplitude and frequency settings have no effect.	



Main parameters

Amplitude: Adjusts the waveform amplitude from 0 to 10mV at a 0.01mV resolution. For all waveforms the amplitude represents the peak to peak value. For example, for a 1mV sine wave the actual waveform varies between +0.5mV and -0.5mV. This correlates with testing requirements in standards.

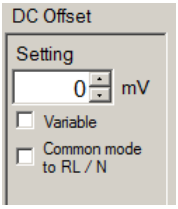
Frequency: The frequency can be set in either Hz or beats per minute (BPM). Changing one will automatically change the other to match. For pulse waveforms (rectangle, triangle, ECG), the frequency can also be referred to as the pulse repetition rate, or heart rate. For some pulse settings the frequency is limited to prevent overlapping pulses.

Pulse Width: Applies to rectangle, triangle and exponential pulse waveforms only. For the rectangle, pulse width is defined as the time between crossing the 50% point in rising and falling edges of the pulse[3]. For triangle pulses, the setting matches the base of the triangle pulse. For exponential pulse, the set pulse width is time constant. Pulse width can be set to down to 2ms[4].

QRS Duration: Allows the setting of the QRS component of the ECG wave in IEC 60601-2-27, in the range of 10 to 120ms, matching the requirements of the standard[5].

T Wave: allows setting of the amplitude of the T-Wave in ECG waveforms, to verify tall T-wave rejection ability of patient monitors according to IEC 60601-2-27. Maximum amplitude is 2.5mV. For the heart rate accuracy test in IEC 60601-2-27, a T-wave component is not required. In this case, set the T-wave to zero.

2.6.2 DC offset setting



This function allows the operator to switch in a dc offset. In the default condition (not variable), only +300mV, 0 or -300mV can be set. In this mode, the dc offset is sourced from an internal “super capacitor” which at least3 minutes of accurate and stable 300mVdc offset to be placed in series with the main

[3] To minimise ringing due to ECG notch filters, rectangle pulses have a rise time of 1ms. This means that a 20ms rectangle pulse will actually have a 21ms base and a 19ms at the top of the pulse. This definition ensures that the pulse integral matches the setting, e.g. a 3mV 100ms pulse will have an integral of 300µVs.

[4] Note the sampling rate is limited to 0.2ms. Therefore a 2ms pulse will have limited time resolution.

[5] This range has increased to include 10ms to allow for the new heart rate test in IEC 60601-2-27:2011 (a QRS of 10ms should not provide any heart rate).

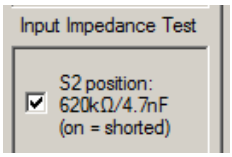
waveform, without impacting the quality of that main waveform. The capacitor is charged while not in use (i.e. when the setting is zero).

In the variable mode, the dc offset is provided by a second channel. This mode is intended only for investigation into the point in which “LEADS OFF” or similar alarms are provided. It is limited to 1000mV.

The “Common mode to RL/N” places the 300mV offset in series with the RL/N as per IEC 60601-2-25, switch position C in Figure 201.110.

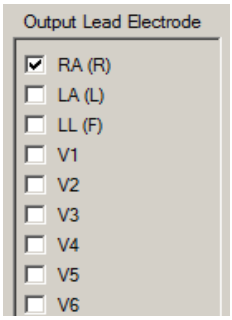
Switch position A in Figure 201.110 of IEC 60601-2-25 is not implemented. This is considered an error in the test circuit, as the output will be loaded by R2, resulting in a reduction in the applied voltage of 2.1%. Instead, users should continue to test with the DC offset in series, as per Figure 201.106.

2.6.3 Input impedance test



This check box allows the user to switch in an impedance of 620kΩ//4.7nF in series with the main function, for testing the input impedance of the ECG device under test. When the check box is ticked, the impedance is shorted. The ±300mVdc offset can be used in conjunction with this test.

2.6.4 Output lead electrode



This section allows the user to select which lead electrode the output is connected to (e.g. terminal P1 in the IEC 60601-2-25, Figure 201.106). Unselected electrodes are connected to the system ground (terminal P2 in Figure 201.106).

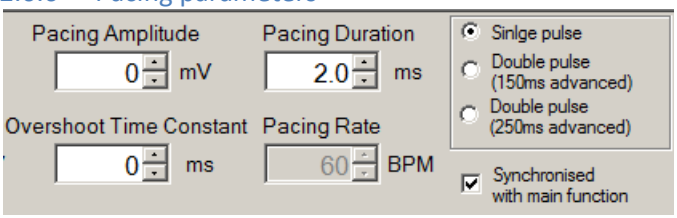
More than one lead electrode may be selected. For example, if it is desired to have Lead I and Lead II have a positive indication, LA and LL can be selected.

Note: In version 4.0, the signal can no longer be output to RL, since this is normally not used for measurement.

2.6.5 Lead electrode impedance

Not used in Version 4.0. In version 3.0, the user could select to include 51k/47nF in series with the output electrodes, as required in IEC 60601-2-51. However, all standards are now harmonized and use the same test circuit, with 51k/47nF only in RL (neutral electrode).

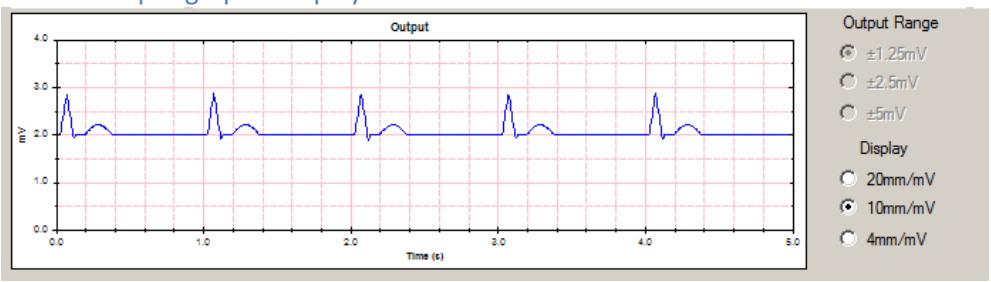
2.6.6 Pacing parameters



In general, a pacemaker pulse can be added to any main function (sine/triangle/ECG etc), with the following parameters:

Pacing amplitude	This can be set in steps of 2 ranging from -700 to +700mV When set to zero the pacing function is turned off regardless of other pacemaker settings. When set at +2 or -2mV the pacing pulse comes from the main 1000:1 divider, which is accurate to better than ±1%. For settings above 2mV, the output comes from Ch2, which has a design accuracy of ±1% or ±5mV.
Pacing Duration	Can be set between 0.1 and 2.0ms, covering the range required by all standards.
Overshoot time constant	Settings from 2ms to 100ms, creates an overshoot according to Method A of IEC 60601-2-27 (0.25 of the pacing amplitude or 2mV, whichever is smaller).
Pacing rate/ synchronized with main function	If the “Synchronized with main function” checkbox is ticked, the pacing pulse will be synchronized with the main function, such as the ECG waveform in IEC 60601-2-27. If this box is not ticked, the user can set the pacing rate independent of the main function (e.g. 80 bpm as required by IEC 60601-2-27, 100bpm according to IEC 60601-2-51).
Single/Double pulses, 150ms and 250ms advanced	This group selects whether single or double pulses are required according to IEC 60601-2-27. If double pulses are required, they can be 150 or 250ms advanced.

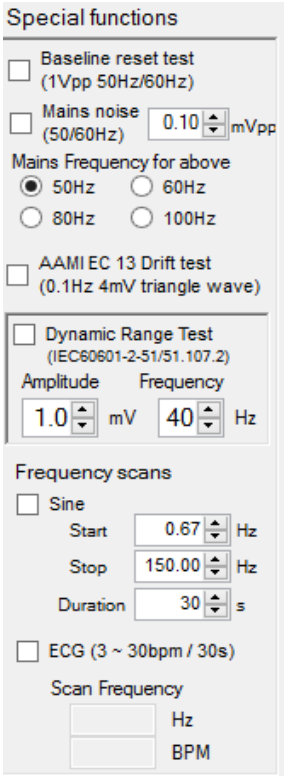
2.6.7 Output graphic display



The output display provides an image similar to that provided by ECGs. The sensitivity of the display range may be set at 4mm/mV, 10mm/mV or 20mm/mV to cover the full range of waveforms offered by the system. The time rate is fixed.

The output display uses the same data as used in the DAC output and serves as a cross check of the selected waveform, and also allows the user to view the original waveform as filters in the ECG device under test can substantially alter the waveform.

Pacing pulses are shown in purple.
For Version 4.0, the output range is fixed at ±5mV.



2.6.8 Special functions

Baseline reset test (sine wave only): When checked the parameters are ignored and a large signal of 1Vpp (0.354Vrms) is applied. It is intended to test the ECG's response to overload, in particular automated resetting of baseline (due to high pass filtering). When unchecked, the system reverts to the previous settings (e.g. 1mVpp 10Hz signal). Mains frequency of the test can be selected from 50Hz or 60Hz.

Mains noise (ECG 2-27 waveform only): When checked adds small sine wave at mains frequency of 50Hz or 60Hz. Range is from 0.05 ~ 0.2mVpp (additional range added for EC 13).
Note: settings of 80Hz and 100Hz are used for calibration of capacitors only, not intended for testing ECGs

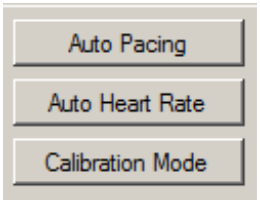
AAMI EC 13 Drift test (ECG 2-27 waveform only): when checked adds 4mVpp 0.1Hz triangle waveform to the ECG signal (for testing baseline drift).

Dynamic Range Test (square wave only): when checked adds a 1mVpp waveform at the frequency indicated (20, 30 or 40Hz), intended for combination with an adjustable square wave for testing Clause 51.107.2 in IEC 60601-2-51.

Frequency scans:
Sine: may be used with IEC 60601-2-51 tests or to test systems with extended frequency response. This system uses a fixed sampling rate of 5kHzwhich has been found to reduce problems of beating from other digital sources. If beating still occurs, a separate analogue input at BNC1 is provided to allow testing with analogue type function generators.

ECG: can be used for testing IEC 60601-2-27 heart rate below 30bpm as indicated in the standard (0~30bpm over 30s).As a frequency of "0" is infinitely long, the scan starts at 3bpm.

2.6.9 Other functions (Auto Pacing, Auto Heart Rate, Cal Mode)



Auto Pacing: This opens a new window for automatically cycling though all the combinations required for pacemaker testing in IEC 60601-2-27 (Clause 50.102.13).

Auto Heat Rate: This opens a new window for automatically cycling though all the combinations required for heart rate testing in IEC 60601-2-27 (Clause 50.102.15).

Calibration mode: Opens a new window (see Section 0)

Recommended use for Auto Pacing
This option is intended to be used in conjunction with a trend mode in a patient monitor. If the patient monitor can reject pacing pulses, the heart rate should not be affected. Therefore, the test should be set up with a mode that has a constant heart rate.

For the tests in IEC 60601-2-27, the tests can be grouped into synchronized (heart rate and pacing is 60bpm), and asynchronized (heart rate 30 bpm, pacing 80 bpm).

In addition, ±2mV pacing pulse uses a separate range. Changing to this range can cause switching transients that can affect the heart rate. Therefore, separately out testing for ±2mV is recommended.

Based on experience, it is recommended to have a change interval of at least 30s. With the selected time, users should verify by simulation that the trend mode will

clearly show up problems (e.g. deliberately set a wrong heart rate for 10s, and verify this is detectable).

Note that most patient monitors will have problems with the overshoot function. Users should experiment first to find the overshoot that the patient monitor can handle, or test this separately (limit the overshoot time to 0ms only).

Recommended use for Auto Heart Rate
As above, tests for the Auto Heart Rate are intended for use with trend monitoring on a patient monitor, and should be grouped according to heart rates.

2.7 Options (5 lead)

The standard equipment covers 12 leads (10 terminals).

Lower cost versions have 5 leads. These options are identical except that the output relays have not been fitted. The outputs are as follow.

- 5 lead: Output to RA, LA, LL, RL and V1 only; switched impedance in the same terminals

The breakout box terminals and impedance for terminals can be made according to request. For the 5 lead options the standard breakout box provides 5 terminals (RA, LA, LL, RL, V1) plus an terminal connected to the circuit ground (not switched, no impedance). This can be used for calibration or as needed during tests. It is the same point as the “GND” 4mm terminal near the USB socket.

The software will detect the option when the USB module is connected, and disable the related software features such as switching for output and lead impedance.

The calibration routine is modified for this equipment. Where the calibration routine indicates connection to RL and RL is not provided (or switched), connect to the circuit ground using the breakout box terminal (if provided) or the 4mm socket marked “GND”.

2.8 Software updates

This manual was written around software version 1.0.0.x. At this time there are no significant variations associated with software updates.

3 Testing to IEC and AAMI standards

3.1 Relation between IEC figures and WhaleTeq SECG

As of 2012, all IEC standards have harmonized the test circuits. There remains some variation in the switch and parts numbering, however the circuit layout and parts are effectively identical.

To be flexible, the WhaleTeq equipment does not use the switch nomenclature in the standards. Rather, the user should simply follow the effective settings. For example, IEC 60601-2-27 may say “Close switches S, S2 and S4 …” which means “connect the function generator, short out both input impedance and dc offset functions”. With the concept of the test in mind, and some experience with using the WhaleTeq system, this translation becomes second nature.

The following table provides a cross references between switches and terminals referred to in the three IEC ECG related standards, the intended function, and settings in WhaleTeq’s Single Channel ECG.

-2-25 / Figure106	-2-27 / Figure105	-2-47 / Figure101	**Function**	**WhaleTeq SECG Settings**
S2	S	S2	Connects the function generator to the ECG.	Automatically connected when function is selected.
S5	S1	None	Shorts out the 100kΩ (allows large signals)	The SECG automatically selects Ch1 for small signals and Ch2 for large signals[6].
S1	S2	S1	Shorts the 620kΩ used for the input impedance test.	Input impedance, S2 checkbox (default condition is shorted)
S3	S4	S3	Shorts out the dc offset circuit	Automatically selected if DC offset is set to zero
S4	S3	S4	Sets the polarity of the dc offset	Automatically selected if DC offset is set to +/-300mV
P1	P1	P1	Output signal	Any selected output lead electrode is connected to P1
P2/P3	P2/P3	P2/P3	Circuit ground	Any unselected output lead electrode is connected to P2
P6	P6	P6	Neutral electrode (RL/N), with series 51k/47nF	Terminal RL/N in the breakout box (pin 4) is permanently connected to GND/P3 via 51k/47nF

[6] If no large signal is required, Ch2 is switched out by relay, to avoid noise from Ch2. Ch1 is always connected.

3.2 Terminals P1, P2 and P6

According to the test circuits in all three standards, terminals P1, P2 and P6 are defined. However, in some of the tests it is unclear if unused electrodes should be connected to terminal P2 or P6. IEC 60601-2-25, Clause 201.12.4.103 (Input impedance) provides an example case. At first the test states that:

> Compliance is checked using the test circuit of Figure 201.106

In that figure, it clearly states that terminals P1 and P2 are for LEAD WIRES, while P6 is intended only for the NEUTRAL ELECTRODE, or RL/N.

However the test then goes on to say:

> Connect the sine wave signal generator to any tested LEAD (P1 and P2) with all other LEAD WIRES connected to the N (RL) LEAD WIRE (P6)

The interpretation here is complicated as a “LEAD” refers to the displayed ECG waveform, not specific electrodes. Using Table 201.106, we can infer that for example, “LEAD V1” involves V1, RA, LA, LL, but not V2 – V6. The interpretation could be then that V1 should be connected to P1, with RA, LA and LL to P2, and V2-V6 are connected to terminal P6 along with RL/N. A more reasonable interpretation would be to follow the diagram and test each LEAD wire in turn (first RA, then LA, LL, V1 etc) with all unused LEAD wires connected to P2.

Similarly, the test for multichannel crosstalk uses confusing English:

> Connect all unused PATIENT ELECTRODE connections via P2 to the NEUTRAL ELECTRODE through a parallel combination of a 51 kΩ resistor and a 47 nF capacitor

This could be interpreted to mean simply use the diagram as shown, since the diagram already has 51kΩ/47nF between P2 and P6, or it could mean an additional 51kΩ/47nF, or could even mean connecting unused LEAD wires to P6 directly.

Currently the SECG provides switching for LEAD wires between terminals P1 and P2 only. It is technically complicated to provide switching for LEAD wires to P6 (it would require an additional set of relays). It is the opinion of WhaleTeq that the standard writers intended that only P1 and P2 be used for LEAD wires (as per the diagram), and additionally that using terminal P6 for unused LEAD wires will have negligible impact on the test.

If users would like to test with unused electrodes connected to P6, it should be possible to create a simple extension to the terminal marked RL/N (P6) for connecting unused electrodes.

3.3 IEC 60601-2-27

Please note this section is written for IEC 60601-2-27:2005. In order to meet publishing deadlines, it is not yet updated to the latest standard. However, the concepts remain the same.

The following table provides some guidance on actual tests to IEC 60601-2-27, including highlighting some apparent limitations in the standard.

Clause	Test	Guidance
6.8.2 bb) 4)	Heart rate accuracy in response to irregular rhythm	The waveforms required to verify manufacturer claims (A1 to A4, originally from ANSI/AAMI) can be accessed using “Special” button (under the list of Main Functions, see 2.6.1). These waveforms have been obtained from the Physionet website.
6.8.2 bb) 5)	Response time to a change in heart rate	The results of this test can occasionally be on the limit. It is possible to have time delays of up to 1s between changing the rate on the PC and the actual output, as the WhaleTeq system implement changes only at the end of a cycle to ensure a smooth transition. It is also possible to have delays of several seconds in the patient monitor. If the result is within 1s of the limit, more accurate methods may be needed such as oscilloscope monitoring of the real time ECG signal (at BNC2) and using this to determine the start time.
6.8.2 bb) 6)	Time to alarm for tachycardia	The waveforms required to verify manufacturer claims (B1, B2 with half and double amplitude) can be accessed using “Special” button in the “Main Function”. These waveforms are downloaded from Physionet website and are identical to the AAMI/ANSI waveforms. Note that the preceding “normal condition” (80bpm) is already built into the waveform (as downloaded from the Physionet website).
50.102.1	Accuracy of signal	For non-linearity, the standard requires tests starting with 10% of the display device followed

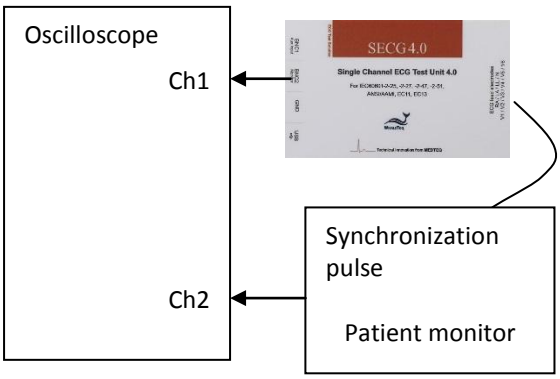
	reproduction (sensitivity, non-linearity)	by 20%, 50% and 100%. However, at 10% the displayed value is typically only 4mm (peak to peak) and there may not be sufficient resolution to accurately perform the test. For this reason it is recommended to reverse the order starting at 100% working down to 10%. Note: this has been corrected in the 2011 edition Filter settings should have no impact on the results for the non-linearity test, but may impact the relationship between set values and displayed values. For this reason, a wide filter (diagnostic) is recommended, for which set values should match displayed values. The test for sensitivity must be performed with the 1mVpp 20Hz sine wave, easy to overlook as the previous test used a triangle wave. Patient monitors with a “monitor” filter setting may have some reduction or variation at 20Hz due to the filter’s characteristics rather than any measurement error in the input circuit. Comparison of results at different frequencies (e.g. 5Hz) or a “diagnostic” filter setting will give clause as to whether any reduction (or increase) is due to the measurement circuit or filter response.
50.102.2	Input dynamic range and differential offset voltage	The standard asks to “adjust the sensitivity” of the equipment so that a 10mVpp signal covers 80% of the display. However, most patient monitors do not have continuously adjustable sensitivities, and come with fixed values such as 2, 5, 10 and 20mm/mV. This is an error which has been corrected in the 2011 edition. In that edition the system is adjusted to provide an 80% of the display at 10mm/mV.

		However, the 2011 edition does not verify the range is ±5mV or the rate of change. So, we can expect this test to be modified again in the future.
50.102.3	Input impedance	For this test noise can be a problem due to the large imbalance in impedance to each lead electrode[7]. Increased efforts to screen the environment may be necessary. The ac filter should be enabled. It is easy to overlook that the test is required at both 0.67Hz and 40Hz. Generally, there is no measurable reduction at 0.67Hz, however, at 40Hz around 10% reduction in the signal when S2 is opened is normal. For ease of measurement, time base settings should be adjusted to suit the frequency (e.g. use 12.5mm/s for 0.67Hz, and 50mm/s for 40Hz).
50.102.4	Input noise	For this test, the USB module can be disconnected from the PC to eliminate any possible noise source. In the unpowered condition, all inputs are connected to RL/N through 51kΩ/47nF resistors are required by the standard. Measurement of noise using printouts or screen may be difficult even at maximum sensitivity as the pixels resolution may be close to the limit. Options include scanning of printouts or using special software which allows the raw data to be inspected.
50.102.5	Multichannel cross talk	For this test, refer to Table 110 in IEC 60601-2-51 to understand the relationship between voltages applied to lead electrodes, and the LEADS indicated on the screen.

[7] An imbalance of impedance degrades the equipment common mode rejection ration, which is the reason why the CMRR test is performed with 51kΩ in one lead only. A value of 620kΩ is very large and hence noise is to be expected. An improved test would see the 620kΩ/4.7nF split into a balanced 310kΩ/2.35nF in each lead, which would still allow input impedance to be measured.

		With the test as initially instructed, there should be no indication on LEAD I of the display. All other LEADS (II, III etc) should have some indication. The 2011 edition has completely updated this test, and is worth checking for reference.
50.102.6	Gain control and stability	Use either a triangle or sine wave (not specified in the standard as the selection does not impact the test).
51.102.7	Time base	Printing devices may have some variation particular around page folds, so it is important to test using the 25Hz waveform in the standard. However, for testing the screen it may be that the width of line prevents individual lines from being seen clearly. The nature of the screen is such that variations are not expected, so a test at 1Hz (e.g. a 100ms rectangle pulse with a frequency of 1Hz) may be sufficient to measure the actual time base. Alternately, reduce the frequency by half (12.5Hz) at which individual lines should be visible.
50.102.8 a)	Frequency response	A common complication with this test is which filter settings to use, as patient monitors often have a variety of filters. Also, mains notch filters may impact the test result, with different results for 50Hz and 60Hz settings. In order to cover “normal use”, a minimum test in “monitor” filter, with and without notch filters is recommended. Note: 2011 edition states that ac filters should be off (if selectable). For the test of Method B (Figure 112), use a triangle pulse waveform and adjust the pulse width to both 20ms and 200ms.
50.102.8 b)	Impulse response	This test is only required for equipment with either a “diagnostic” filter” or an “ST filter”

		setting which extends the low frequency response down to 0.05Hz. A “monitor” filter setting or any filter above 0.05Hz will fail the test. Both simulations and test experience indicate that the typical 0.05Hz filter will only marginally pass the test. At the same time, the 0.1mV (100µV) offset and slope are difficult to measure accurately. For most accurate results, access to raw data may assist in determining compliance.
50.102.9	Calibration voltage	The standard appears to require a calibration voltage, but in the last sentence provides an exception for patient monitors that provide a gain indication. Virtually all patient monitors use this exception, making the clause not applicable.
50.102.10	Common mode rejection ratio	Test requires a separate box available from WhaleTeq.
50.102.11	Baseline reset	For this test use the “Baseline reset test” checkbox as shown in Section 2.6.8 (Special functions). Prior to using this checkbox, set up a 10Hz, 1mVpp sine wave as instructed. The 1V overload will be present whenever checkbox is ticked. The mains frequency can be selected from 50 or 60Hz. The selection of frequency is not critical for the test.
50.102.12	Pacemaker pulse display capability	This test may require settings in the patient monitor to be enabled. To perform this test correctly, the pacemaker pulses should be applied without any other signal. However, this may be an error in the standard as one of the effects of pacemaker pulses can be to distort the ECG signal. It is recommended to perform the test together

		with a 1mVpp “ECG 2-27 signal”. In order to test according to the standard, it is also possible to select any function (sine, triangle, ECG etc) and simply set the amplitude to zero (0.00mV). Settings associated with the pacing function can be found in Section 0 (Pacing parameters).
50.102.13	Rejection of pacemaker pulses	Again this test may require special settings in the patient monitor. There are a large amount of combinations required for this test. An “Auto Pacing” function (see 2.6.9) has been provided to reduce operator time in testing. However, some experimentation is recommended to decide on groups of settings which suit the patient monitor. Settings associated with the pacing function can be found in Section 0 (Pacing parameters). Pacing overshoot “recharge time constant” is limited to Method Aaccording 50.102.13 (k), see Section 1.2 in this manual for explanation.
50.102.14	Synchronizing pulse for cardioversion	This test requires the measurement of delay between the real ECG signal and the pulse output by the patient monitor for interfacing to other medical devices. The real ECG signal can be monitored at BNC2: 

50.102.15	Heart rate range, accuracy, and QRS detection range	For this test, the “ECG 2-27” function should be used, with the “T Wave” amplitude to zero, while the heart rate (frequency), amplitude and QRS duration are adjusted over the range required by the standard. The test for heart rates between 0-30bbpm over 30s can be performed with the “Rate scan (ECG)” check box in the list of Special Functions. For best results, the Main Function should be “Off” before starting the test. This function starts at 3bpm (since 0bpm is infinitely long). As for 50.102.13, there are a large amount of combinations required for the main rate test. An “Auto Heart Rate” function (see 2.6.9) has been provided to reduce operator time in testing. It is recommended to use only one heart rate and vary the other settings (amplitude and QRS duration). It should be noted that main difficult of the patient monitor will be at the lowest amplitudes (0.5mVpp) and longest QRS durations (120ms), as this produces the weakest slope which patient monitors use to trigger the heart rate.
50.102.15	Heart rate range, accuracy, and QRS detection range (continued)	Note: the waveform in Figure 119 is not a simple triangle pulse and the peak of the waveform is 0.875 of the amplitude setting. Some manufacturers may have based their design on a simple triangle pulse which may explain small differences in test results.
50.102.16	Output display	No special guidance.
50.102.17	Tall T-wave rejection	This test is intended to verify that the patient monitor shows the correct heart rate in the presence of a high T-wave. At some point, most patient monitors will treat the high T-wave as new QRS pulse, and hence double count the heart rate (e.g. display 160bpm for an 80bpm input). Note a T-wave of 1mV will actually appear higher than the QRS with an amplitude of 1mV due to the characteristics of Figure 119.

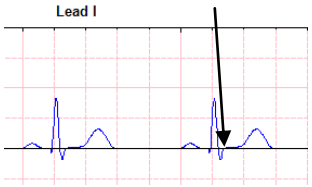
Note: In the future it is planned to update this table to the IEC 60601-2-27:2011 edition

3.4 IEC 60601-2-47

At this time, no special guidance is provided for IEC 60601-2-47. It may be included in future editions of this manual. Refer to similar tests in IEC 60601-2-27 for guidance.

3.5 IEC 60601-2-51

At this time, limited special guidance is provided for IEC 60601-2-51. Detailed guidance may be included in future editions of this manual. Refer to similar tests in IEC 60601-2-27 for guidance. At this time, the following key points are noted:

Clause	Test	Guidance
51.102.1	Input impedance	There is a discrepancy between the requirements specification (-18%) and Table 113 (-6.7%). The rational indicates Table 113 is correct, however many ECG systems record some significant reduction at 40Hz, and may not pass Table 113. A limit of 10% seems reasonable.
51.105.3.2	Impact of notch filters	This test should be done with the multichannel system. The requirement refers to the positive overshoot which can be seen just after the S peak (at the start of the ST segment): 

4 Calibration, software validation

The WhaleTeq SECG 4.0 has undergone a detailed system validation including software. A report for this can be provided on request.

Prior to shipping, each unit is tested for component values and output voltages, using a calibrated precision multi-meter. As WhaleTeq cannot provide ISO 17025 accredited calibration, laboratories which are required to follow ISO 17025 should perform calibration either periodically or on a before use basis, following normal procedures and practice. The extent of calibration may be limited depending on the needs of the laboratory.

As the calibration procedure is complicated, a software assisted calibration mode is provided. The software sets up the SECG as required for the particular tests, and instructs the user on what measurement to make (e.g. measure resistance between RA and RL).

No.	Item	Nominal	Limit	Result	Error	Verdict
#1	*Test location:	---	---	MEDTEQ, Ise Japan	---	---
#2	*Date (yyyy/mm/dd):	---	---	2013/07/19	---	---
#3	*Reference equipment:	---	---	MQ-014	---	---
#4	*Room temperature, °C:	---	---	27	---	---
#5	*Room humidity, %RH:	---	---	51	---	---
#6	*Tests by:	---	---	Peter Selvey	---	---
#7	*SECG Serial No.	---	---	2013-011	---	---
#8	RL Resistance, kΩ:	51.00	1%	51.20	0.4%	Pass
#9	Input imp. rest., kΩ:	620.0	1%	620.1	0.0%	Pass
#10	RL Capacitance, nF:	47.0	5%	46.8	-0.4%	Pass
#11	Input imp. cap., nF:	4.70	5%	4.78	1.7%	Pass
#12	* Change to mVdc	---	---	None required	---	---
#13	Output voltage, mVpp:	0.500	1%	0.502	0.4%	Pass
#14	Output voltage, mVpp:	1.000	1%	1.001	0.1%	Pass
#15	Output voltage, mVpp:	2.000	1%	2.005	0.2%	Pass
#16	Output voltage, mVpp:	3.000	1%	3.011	0.4%	Pass
#17	Output voltage, mVpp:	4.000	1%	4.007	0.2%	Pass
#18	Output voltage, mVpp:	5.000	1%	5.009	0.2%	Pass
#19	Output voltage, mVpp:	7.000	1%	7.011	0.2%	Pass
#20	Output voltage, mVpp:	10.000	1%	10.004	0.0%	Pass
#21	Fixed DC offset, mV:	300.0	1%	300.0	0.0%	Pass
#22	Variable DC offset, mV:	+200	5%	197	-1.5%	Pass
#23	Variable DC offset, mV:	+600	5%	598	-0.3%	Pass
#24	Variable DC offset, mV:	+1000	5	998	-0.2%	Pass
#25	Variable DC offset, mV:	-200	5%	-204	2.0%	Pass
#26	Variable DC offset, mV:	-600	5%	-604	0.7%	Pass
#27	Variable DC offset, mV:	-1000	5	-1003	0.3%	Pass
#28	*Pre-divider out, Vdc	10.000	---	10.003	---	---
#29	Divider ratio:	1000	0.2%	1000.1	0.0%	Pass
#30	Frequency, Hz:	10.00	1%	10.004	0.0%	Pass
#31	Frequency, Hz:	40.00	1%	40.018	0.0%	Pass
#32	Overall Result:	22	---	22	---	Pass

The user then enters the results into the form provided, and the software checks if the results are within allowable limits. When complete, the results of calibration are automatically copied to the notepad and stored in a text file at:

c:\WhaleTeq\SECG_Cal_yyyymmdd.txt

where “yyyymmdd” is the date based on the PC’s system. If a fixed width font such as “Courier New” is used, the data appears aligned.

The following manual procedure is retained here for reference and explanation. The calibration mode does not include pacemaker rise time, which is included in the manual procedure here.

Calibration procedure:

Parameter	Nominal value, tolerance	Method
RL/N resistance	51kΩ ± 1%	The 51kΩ can be measured between any lead electrodes and RL/N terminals. Note: the resistors used are usually accurate to 0.1%, but the measured value will be closer to 51.22kΩdue to the inclusion of a 220Ω resistor used for dc offset. This remains in tolerance.
Lead impedance capacitors	47nF ±10%	The 47nF can be measured between RA and RL/N using a calibrated capacitance meter, at 1kHz.
Input impedance resistor	620kΩ±2%	This can be measured as follows: • Set Main function to "Off" • Set output to RA • Open switch S2 (input impedance test) • Measure the resistance between RA and LL
Input impedance capacitance	4.7nF±10%	Measure as for the 620kΩ above, using a capacitance meter at 1kHz. Note: there is about 100pF stray capacitance in the circuit which is included in the measurement. However, even with this the measured result is within the limit.
Precision divider ratio	1000:1 ±0.2%	Resistance values are specified as 100kΩ and 100Ω ± 0.1%, but these cannot be verified once in circuit. An alternate method is used to verify the accurate ratio: • Set up a 10mVpp 0.1Hz squarewave to output RA • Using the Fluke 8845A or equivalent precision meter, measure and record the peak to peak voltage at BNC2 by zeroing during the negative cycle, and measuring at the positive cycle (nominally 10Vpp). • Repeat this measurement at the output between RA and LL (nominally 10mV) • Calculate the ratio and confirm it is 1000:1 ±0.2%
Output	Setting ±1%	Method:

voltage		• Set up 0.5mVpp 0.1Hz squarewave, output to RA • Measure the peak to peak output between RA and LL, using the Fluke 8845A or equivalent, record this as output mVpp • Repeat for 1, 2, 5, and 10mVpp • Confirm all values are within 1% or 5µV of the set value Note: the Fluke 8845A has suitable accuracy at 10mVpp but has borderline accuracy at 1mVpp and lower. An alternate method is to measure the output at BNC2 and then use the divider ratio above.
DC offset (fixed ±300mV)	300mV ±1%	Method: • Set the equipment to "Off" • Select +300mV • Measure the voltage between RA and LL Note: the DC offset is sourced from an internal super capacitor which will discharge after ~10min. Tests in the standard are typically <<2 minutes.
DC variable	Setting ±5mV or 1%	Use the following procedure: • Set the equipment to "Off" • Select the "Variable" checkbox • Set to +200mV dc offset • Confirm the value is 200±5mV • Repeat for +600, +1000, -200, -600 and -1000mV
Output frequency	Setting ±1%	Method: • Set up 1mVpp 40Hz sine wave • Measure the frequency at BNC2 using any appropriate meter Note: this verifies the system clock is accurate. Verification of other frequencies or timing is not as this is covered by software validation, although users are free to measure other frequencies and timing. The use of 40Hz is recommended to avoid beating with mains frequency.

Pacemaker pulse characteristics	Voltage ±10%, pulse width ±1%, rise time <10µs, overshoot <5%, settling time <5µs	The pacemaker pulse can be observed directly at the terminals RA and LL (with the output to RA terminal). Use a setting of +700mV 2ms, so the pulse can clearly be seen above any oscilloscope noise. Measure the amplitude, rise and fall time and overshoot.

5 Trouble shooting

Problem	Resolution
USB module (test unit) not recognized (USB driver is installed correctly)	Recognition of USB devices needs to be done in order: 1) Close WhaleTeq software if open 2) Disconnect the USB module for ~2s 3) Reconnect the USB module 4) Wait for the recognition sound 5) Start WhaleTeq software
USB module stops responding	Move the main function mode to “Off” and then return to the function being used. If this does not work, close WhaleTeq software, disconnect the USB module, reconnect the USB module and re-start the USB module.

6 Contact details

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